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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,658	07/22/2002	Alvin Berger	112843-044	6858

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BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
03/25/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/089,658	BERGER ET AL.	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,13-16,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11,13-16,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt of amendments to the claims and Applicant's arguments dated 12/17/07 is acknowledged.

Status of claims: claims 1,3-11,13-16,18 and 19 are pending in the application.

Claim Rejections - 35 USC § 112

In view of cancelling the claims the rejection of claims 17 and 23-25 under 35 U.S.C. 112, first paragraph, is herein withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In view of amending and cancelling the claims the rejection of claims 1, 20 and 23 are rejected under 35 U.S.C. 112, second paragraph is herein withdrawn.

1. In view of Applicant clarification and arguments, the rejection of claim 11 under 35 U.S.C. 112, second paragraph is herein withdrawn.

2. Claim 19 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the step of “synthesizing” as a step in a method for “producing”. Since synthesizing means producing, the claim is confusing and unclear.

Claim Rejections - 35 USC § 102

1. In view of reciting the steroidal or non-steroidal anti-inflammatory drug (NSAID) in the amendment of claim 1, the rejection of claims 1 and 4-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Di Marzo V. 2-Arachidonoyl-glycerol as an "endocannabinoid": limelight

for a formerly neglected metabolite, Biochemistry (Mosc). 1998 Jan;63(1):13-21 is herein withdrawn.

2. In view of reciting the steroidal or non-steroidal anti-inflammatory drug (NSAID) in the amendment of claim 1 and 16 and cancelling claim 17, the rejection of claims 1, and 15-17 under 35 U.S.C. 102(e) as being anticipated by Eric Murillo-Rodriguez et al. Anandamide modulates sleep and memory in rats, Brain Research, Volume 812, Issues 1-2, 23 November 1998, Pages 270-274 is herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

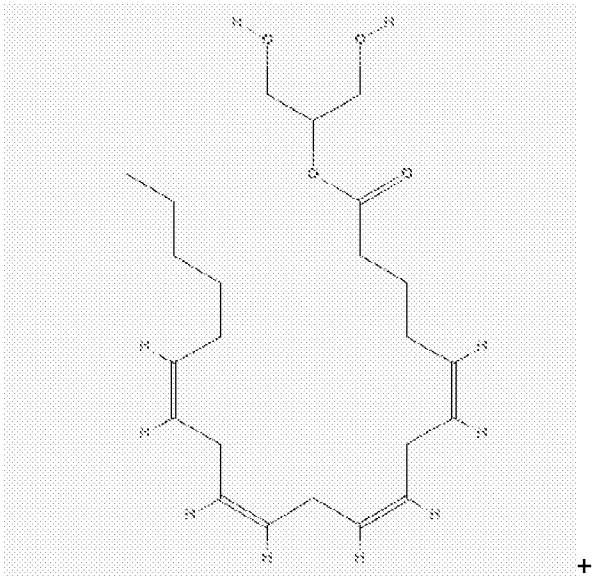
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time

a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 3-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Marzo V. 2-Arachidonoyl-glycerol as an "endocannabinoid": limelight for a formerly neglected metabolite, Biochemistry (Mosc). 1998 Jan;63(1):13-21 (hereinafter Marzo) in view of Burch et al. US 6552031 (hereinafter Burch)

Marzo teaches that alternative precursor for arachidonic acid, 2-arachidonoyl-glycerol has cannabimimetic activity. Marzo discloses that a composition comprising the precursor of arachidonic acid have led to the proposition of a role of the monoglyceride as an "endocannabinoid", starting from its newly discovered pharmacological properties in both central and peripheral tissues and ending with studies on the possible biosynthetic pathways for its formation. Also considered are possible interactions with another arachidonic acid-derived endogenous cannabinoid, anandamide.



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The article discloses the importance of the same sterochemical configuration of AarG which is diglycerides bearing AA in *sn*-2 position. AArG precursors for 2-AG may be formed

from the enzymatic hydrolysis of *sn*-2-AA-containing phosphatidic acid (PA) coming also from the PLD-mediated conversion of N-ArPE into ANA. Again, in this case the two "endocannabinoids" may be produced simultaneously (see page 6, and Fig. 3). Marzo also recognized the palmitoylethanolamide and leamide in the process of detecting the importance of anandamide precursors as agonist for cannabinoid receptors (see page 3). Arachidonic acid is known to be naturally occurring in dietary animal source.

Marzo does not disclose a combination of an anandamide precursor and NSAID.

Burch teaches that combinations of analgesic drugs causes synergism of its analgesic effect. Burch exemplifies the combinations by using oxycodone and NSAID's (rofecoxib).

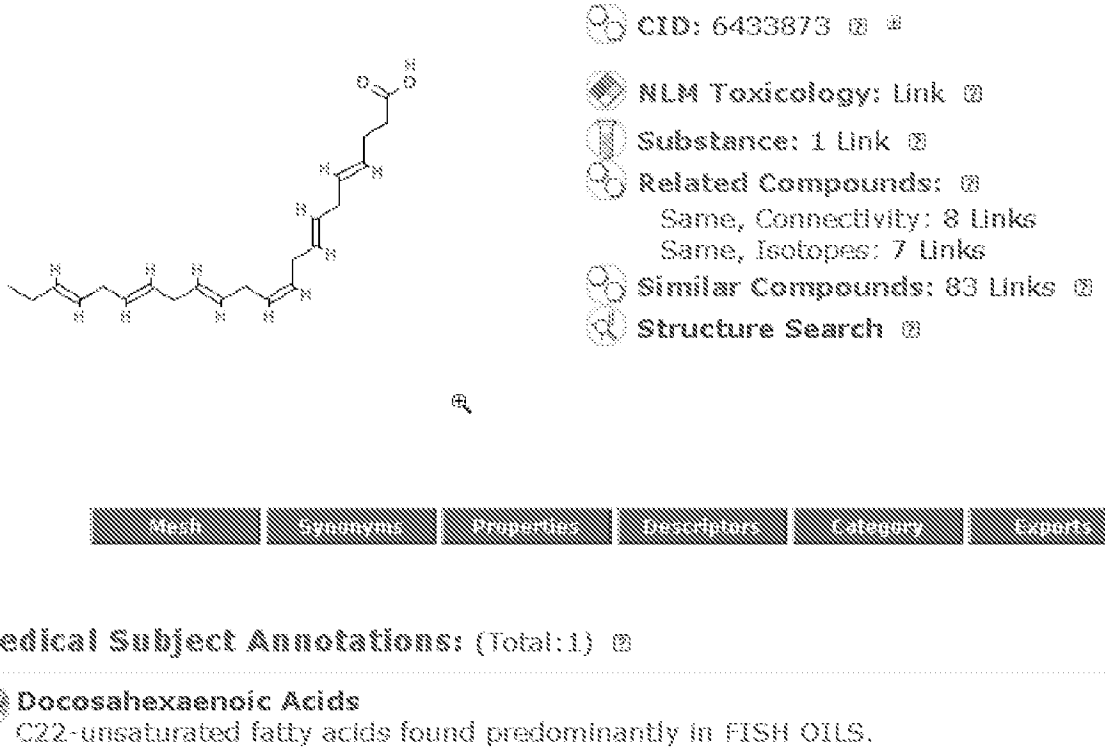
It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine an anandamide and/or an anandamide precursor with NSAID's to enhance the analgesic effect of both drugs. It would also be a good motivation to the skilled artisan to replace oxycodone with anandamide as anandamide derivatives and precursors do not have the addictive characteristics of oxycodone. The ordinary skilled man in the art would have expectation of success since NSAID's have been combined with other analgesic drugs successfully and enhanced the effect of analgesia for the patients.

2. Claim 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Marzo V. 2-Arachidonoyl-glycerol as an "endocannabinoid": limelight for a formerly neglected metabolite, Biochemistry (Mosc). 1998 Jan;63(1):13-21 (hereinafter Marzo) in view of in view of Burch et al. US 6552031 (hereinafter Burch) and further in view of Kyle et al WO 94/28913 (hereinafter Kyle).

Marzo in view of Burch has been discussed supra.

Both references do not teach a therapeutic composition for oral administration. In addition, the reference is deficient in disclosing the way of manufacturing the therapeutic or the nutrient.

Kyle discloses a method of treating patients suffering from neuro-degenerative ailments associated with DHA or arachidonate (ARA) deficiency (abstract and page 6 lines 1-30, continuing to page % lines 1-5). The oils can be administered as a pharmaceutical composition, as a dietary supplement, or in the form of a food product by replacing a portion of the vegetable oil or fat thereon. The preparation method includes purifying the oil and extracting (which is equivalent to the synthesizing step), see pages 16 and 17.



Kyle teaches a method of treating neurological disorders, including certain neurodegenerative diseases and psychiatric disorders, by administering a composition comprising a therapeutically effective amount of a single cell microbial oil comprising docosahexaenoic acid (DHA), a single cell oil comprising arachidonic acid (ARA) or a combination of DHA- and ARA-containing oils, to a person in need of such treatment. The oils can be administered as a pharmaceutical

composition, as a dietary supplement, or in the form of a food product by replacing a portion of the vegetable oil or fat thereon. The preparation method includes purifying the oil and extracting (which is equivalent to the synthesizing step), see pages 16 and 17.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to purify the naturally occurring arachidonic acid derivative disclosed by Marzo or use the ARA disclosed by Kyle to treat different disorders as disclosed by the Kyle and make an oral therapeutic product as disclosed by Kyle to advance the treatment of these ailments and facilitate to patients taking their therapeutic needs in an easy oral dosage form or nutrient.

Response to Arguments

3. Applicant's arguments filed 12/17/07 have been fully considered but they are not persuasive. Applicant argues that:

- The skilled artisan would recognize that the term "synthesis" as used in Claim 19 does not simply means "producing." Instead, the skilled artisan would recognize that the "synthesizing" of Claim 11 refers to the formation of a chemical compound by combining several simpler compounds or elements through chemical synthesis.

To respond: claim 14 from which claim 19 depends recites “a method of producing” wherein the steps are: obtaining the precursor, obtaining the NSAID, and preparing the composition made of the two components. Claim 19 adds a step of synthesizing the precursor. The language of claim 19 is confusing since producing, preparing, and synthesizing are alternatives to the same meaning. Applicant's explanation that synthesizing should be understood as formation of chemical compounds is not acceptable especially that the specification does not define the

synthesizing step as such, accordingly it does not particularly point out and distinctly defines the metes and bounds of the claim.

- With respect to Claims 1-13, Applicants respectfully submit that there exists no reason why the skilled artisan would combine Di Matzo and Butch to arrive at the present claims. For example, because the Patent Office admits that Di Matzo does not disclose a combination of an anandamide precursor and an NSAID, the Patent Office cited Butch to cure the deficiencies of Di Matzo.

To respond: Burch teaches that combinations of analgesic drugs cause synergism of its analgesic effect. Burch exemplifies the combinations by using oxycodone and NSAID's (rofecoxib). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine an anandamide and/or an anandamide precursor with NSAID's to enhance the analgesic effect of both drugs. It would also be a good motivation to the skilled artisan to replace oxycodone with anandamide as anandamide derivatives and precursors do not have the addictive characteristics of oxycodone.

- The Patent Office alleges that Burch teaches the combination of oxycodone and rofecoxib. However, Applicants respectfully submit that, in contrast to the Patent Office's assertion, the skilled artisan would have no reason to replace oxycodone with anandamide to arrive at the present claims because opioid analgetics, such as oxycodone, may be deployed as a substitute for heroin or morphine, and can results in similar negative side-effects. For example, opioid analgetics can be extremely addictive to the user and can result in adverse reactions including+ respiratory depression, orthostatic hypotention, hallucinations, hyperalgesia, delirium, etc.

To respond: The office action is clear regarding addictive effect of oxycodone and expresses clearly that this is a good motivation to a person of ordinary skill in the art to replace oxycodone

with an anandamide precursor to avoid addiction and side effects in addition to establishing the disclosure of Burch that combinations of analgesic drugs cause synergism of its analgesic effects. Note that Burch did not specify a combination of analgesics comprising narcotic analgesics but generalized the disclosure to encompass all analgesic drugs.

- Regarding claims 14-25, applicant argues that Kyle merely specifies the use of non-modified polyunsaturated acids like DHA or ARA. See, Kyle, Abstract.

To respond: ARA is one of the compounds comprised by the precursor in the Markush group recited in the instant claims wherein the structure is includes 20-carbon chain and four *cis* double bonds; the first double bond is located at the sixth carbon from the omega end as recited in the claims.

- **The arguments regarding rejection under 35 USC §102 renders moot in view of withdrawing the rejection.**

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618